

REMARKS

In the Office Action issued on May 7, 2007, the Examiner:

- rejected Claims 9 through 11 under 35 U.S.C. §101 as being directed to non-statutory subject matter;
- rejected Claims 1 through 4, 7 through 9, and 13 under 35 U.S.C. §102(e) as being anticipated by Duran (United States Patent No. 7,125,418);
- rejected Claims 1, 2 and 7 through 9 under 35 U.S.C. §102(b) as being anticipated by Moll (United States Patent No. 6,287,334);
- rejected Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Duran; and
- rejected Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll.

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections. A Request for Continued Examination (RCE) is being filed along with this Reply and Amendment.

Reconsideration of the application for patent is requested.

Interview with Examiner

As a preliminary matter, the Applicants would like to thank the Examiner for the in-person interview held with the undersigned attorney at the Patent and Trademark Office on June 5, 2007. During the interview, the undersigned attorney and the Examiner discussed the cited references and potential amendments to the claims. While no agreement was reached, the Examiner's suggestions, as reflected in the Interview Summary issued at the interview, have been evaluated and are considered helpful.

Rejection of Claims 9 through 11 under 35 U.S.C. §101

The Examiner rejected Claims 9 through 11 under 35 U.S.C. §101 as being drawn to non-statutory subject matter. Specifically, the Examiner indicated that:

"[c]laiming a comparison to a portion of the body is non-statutory subject matter. Claims 9-11 each recite, "opening is less than...of the cross-sectional area of said

body vessel." Applicant has compared the device directly to the body vessel."

The applicants thank the Examiner for the explanation of this rejection offered during the June 5, 2007 interview. In light of the Examiner's explanation, the applicants have herein amended each of these claims to reflect the Examiner's suggestion made in the Office action.

These amendments fully overcome this rejection of the claims. Accordingly, the Applicants respectfully request that the Examiner remove this rejection.

Rejection of Claims 1 through 4, 7 through 9, and 13 under 35 U.S.C. §102(e)

The Examiner rejected Claims 1 through 4, 7 through 9, and 13 as being anticipated under 35 U.S.C. §102(e) by Duran.

The Applicants have herein amended independent claims 1 and 13 to clarify that the leaflet "at least partially defining a valve orifice that regulates said fluid flow" and that the opening is "spaced from the valve orifice along an axis of said implantable medical device."

These amendments achieve the Examiner's suggestion of providing location language for the retrograde flow opening.

Applicants respectfully assert that Duran fails as an anticipatory reference for independent Claims 1 and 13 at least because it fails to disclose the newly added location requirement for the retrograde flow opening. Each of Claims 2 through 4 and 7 through 9 ultimately depend from independent Claim 1 and, therefore, also include this limitation. As a result, Duran also fails to anticipate these claims.

At least for this reason, the rejection of Claims 1 through 4, 7 through 9, and 13 as being anticipated under 35 U.S.C. §102(e) by Duran is improper. Applicants respectfully request withdrawal of this rejection of the claims.

Rejection of Claims 1, 2 and 7 through 9 under 35 U.S.C §102(b)

The Examiner rejected Claims 1, 2, and 7 through 9 as being anticipated under 35 U.S.C. §102(b) by Moll.

In the response to the previous Office action, the applicants amended independent claims 1 and 13 to clarify that the opening "permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction."

As discussed in the June 5, 2007 interview, the Applicants respectfully assert that Moll fails to anticipate any of the rejected claims at least because it fails to disclose this requirement of Claims 1 and 13.

Referring to the Examiner's markup of Moll, included in the Office action as Attachment 2, the opening referred to by the examiner (near element 16) would only permit fluid flow to *enter* the space between the inner 12 and outer 14 walls (best illustrated in Figure 1). The opening would not permit fluid flow *to pass through* the medical device. Indeed, Moll explicitly describes the disclosed device as *preventing* such flow through the medical device upon entering this space:

"In this way between heartbeats, which force the blood through the venal system, any blood flowing in the opposite direction to the blood stream opens the proximal end of the stoppage element thereby forcing the sidewalls apart to enter the temporary blood storage area, *instead of passing through the device to leak back into the blood vessel in the direction from where it has just been pumped.* Since opening of the blood flow stoppage element effectively closes off the blood vessel, a very effective valve is provided." (Moll, c.1, line 65 through c.2, line 7) (emphasis added).

Applicants respectfully assert that Moll fails as an anticipatory reference for independent Claims 1 and 13 at least because it fails to disclose the limitation that the opening "permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction." Each of Claims 2 and 7 through 9 ultimately depend from independent Claim 1 and, therefore, also include this limitation. As a result, Moll also fails to anticipate these claims.

At least for this reason, the rejection of Claims 1, 2, and 7 through 9 as being anticipated under 35 U.S.C. §102(b) by Moll is improper. Applicants respectfully request withdrawal of this rejection of the claims.

Rejection of Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a).

The Examiner rejected Claims 5, 6, 10, 11, 14, and 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Duran.

Applicants respectfully assert that the Examiner's rejection is rendered moot by the amendment made to independent Claims 1 and 13 herein. Each of the rejected claims depends from one of these amended independent claims. None of the cited references, taken alone or in combination, teach the now required location for the retrograde flow opening. Accordingly, no single reference or

combination of references can properly serve as a basis for an obviousness rejection under §103(a).

Reconsideration is requested.

Rejection of Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a).

The Examiner rejected Claims 3 through 6, 10, 11, and 13 through 15 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll.

Applicants respectfully that the Examiner's rejection is rendered moot by the amendment made to independent Claims 1 and 13 herein. Each of the rejected claims depends from one of these amended independent claims. None of the cited references, taken alone or in combination, teach the now required location for the retrograde flow opening. Accordingly, no single reference or combination of references can properly serve as a basis for an obviousness rejection under §103(a).

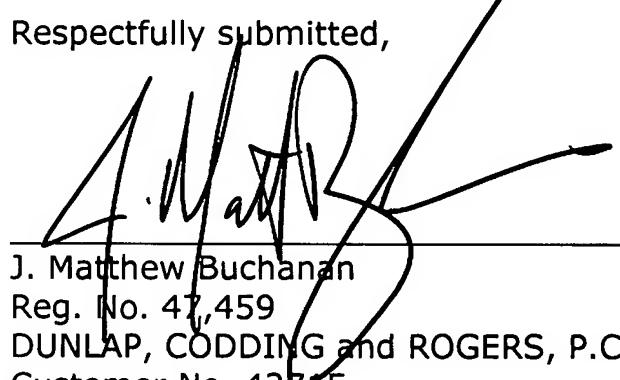
Reconsideration is requested.

CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the May 7, 2007 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request their reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,



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